PSS Company Overview

December 25, 2013

Precision System Science Co., Ltd.

Precision System Science Co., Ltd.

Corporate Profile

Vision & Mission

- **PSS seeks to contribute to society by expanding knowledge in the genetic diagnosis domain through developing and providing automated diagnostic products for “Anytime, Anywhere, Anyone” aiming to further utilize the resulting genetic information.**

History

Founded R&D type of business: Accumulate know-how in automated IVD products

✓ PSS founded July 17, 1985

Immunoassay diagnostic system is the origin of PSS business

①Start up

Formed Global Business Relationships: Non-exclusive partnership strategy based on original patented technology

✓ IPO February 28, 2001

Invented Magtration® Technology to commercialize a highly sensitive immunoassay system by using magnetic particles as a carrier

- Focused on developing potential a DNA based diagnostic system to apply Magtration technology
- Commercialized the industry's first automated DNA extraction system and entered into OEM contracts with Roche, Qiagen, Life Technologies, Abbott, Toyobo, Mitsubishi Chemical Medience (Immunoassay field).
- Many PSS original technologies have been applied for or registered for patents.
- More than 10,000 automated DNA extraction systems have been sold worldwide.

②Establish Business Model

Promote fully automated products including reagent as a system integrator in genetic diagnosis domain
Laboratory (R&D) automation field → Full scale business in IVD market

✓ Establish Odate Reagent Center October, 2013

Promote fully automated DNA testing system by leveraging Magtration® Technology

Developed fully automated DNA testing & analysis system after IPO

Odate Reagent Center is in the process of entering into full scale production for Diagnostic Reagent manufacturing.

③Business Expansion

PSS Worldwide Sales Network (Sales & Customer Support)

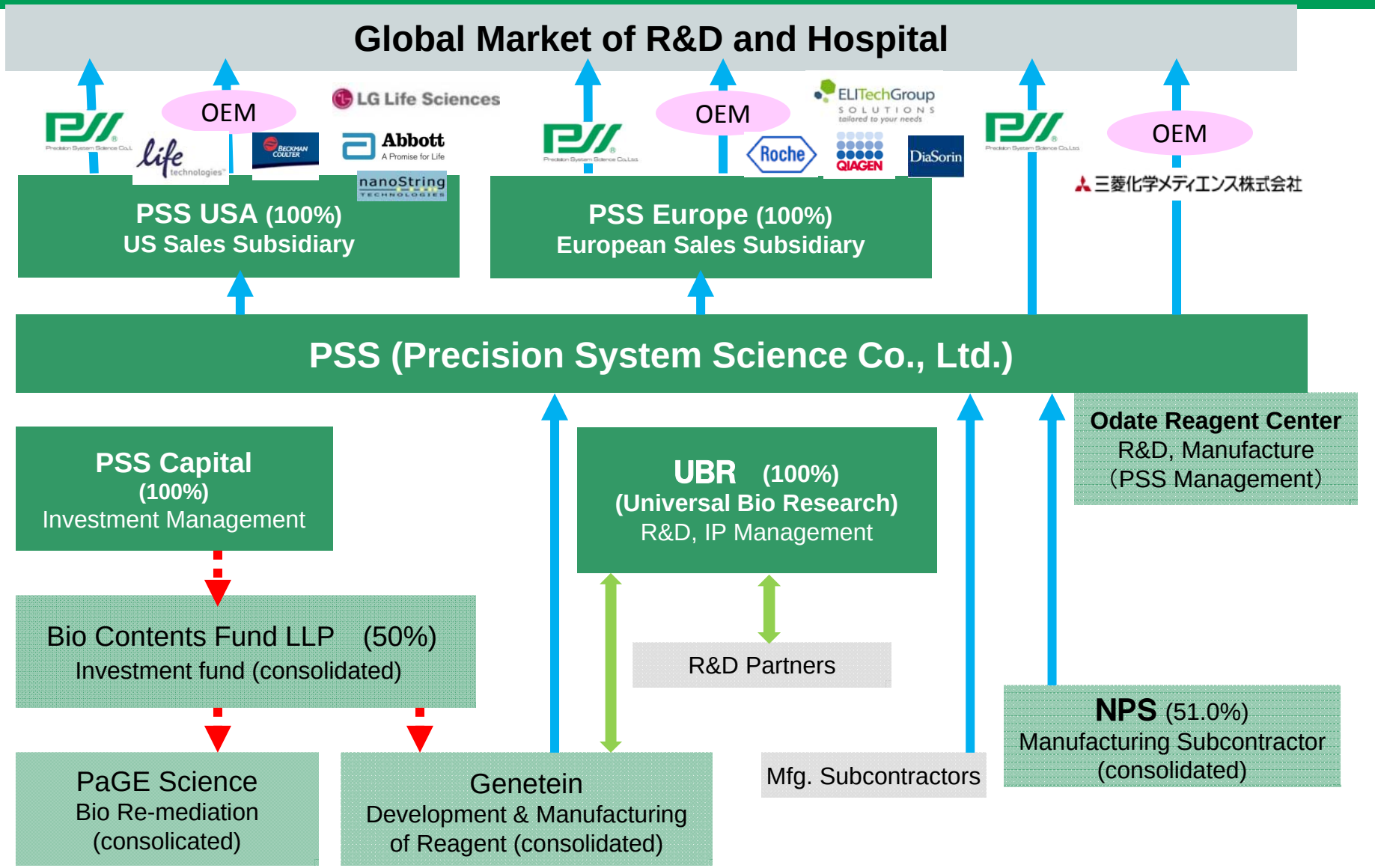
PSS Europe GmbH
Woerrstadt, Germany

PSS Head office

PSS USA, Inc.
Pleasanton, CA, USA

Precision System Science Co. Ltd.	**88 Kamihongo, Matsudo-shi, Chiba 270-0064, JAPAN** **http://www.pss.co.jp/** **+81-47-303-4800**
Capital	Yen 8.2Billion /US$82Million @100JPY/USD (as of 06/30/2013)
Annual Turnover, consolidated	Yen 4.0 Billion /US$40Million @100JPY/USD (as of 06/30/2013)

PSS Group Network



Employees	151 excluding contracted (as of 06/30/2013)

Domestic Partners/Affiliates

Laboratory (R&D) Automation Products

Automated DNA Extraction System

PSS DNA extraction systems have been incorporated into OEM customers product lines. For example, Roche or Qiagen as partners reward PSS with continued consistent business

Automated Sample Preparation System (for DNA Sequencer, etc.)

(Under development) (Under development)

Plastic Consumables / Reagents

Plastic consumables are supplied to OEM Partners.

Reagents for DNA extraction are manufactured and sold under PSS brand.

Clinical Diagnostic Products

POCT Immunoassay Diagnostic System

Realize simultaneous
diagnostic for cardiac disease

Steady sales worldwide.
CE-IVD and FDA clearance.

Fully Automated Diagnostic System (under development)

DNA Analysis System / Sample prep for sepsis

【DNA analysis system】

【Sample prep for sepsis】

(under development)

Abbott
A Promise for Life

Pre-packed Reagents / Plastic Consumables

Sample preparation reagent
for the fully automated
diagnostic system have been
developed for manufacture
and sale.

Pre-packed Reagents

reagent cartridge

PCR cassette

What is the PSS contribution to the society?

■ **More than 10,000 automated DNA extraction systems based on Magtration® technology are sold to OEM customers worldwide.**

High Throughput NAT System: Roche PCR + PSS Magtration

Dramatically decreased the number of HIV/HCV/HBV after blood infusion

◎Up to 5 million blood samples per year.

(PSS instrument is not in use any more.)

WHO swine influenza guideline

PSS OEM product is recommended for hospitals worldwide

◎ Worldwide share of 50% (PSS estimate)

→ Recognized as the standard of DNA extraction system

World Health Organization

CDC protocol of realtime RTPCR for influenza A(H1N1)

28 April 2009
revision 1 (30 April 2009)
revision 2 (6 October 2009)

DNA Testing in forensic examination

Genetic analysis is spreading more and more on a global basis. Also after the Tohoku Earthquake in 2011, DNA testing fully contributed to personal identification of unknown bodies.

◎Approx. 210,000 DNA testing have been processed in 10 years; which is 80 times larger as 10 years before.

→The accidental error have been improved dramatically from 1.2 person per thousand to 1 person per 4.7 trillion

Expand the applicable field

Automated DNA extraction system based on Magtration® technology have been expanding its applicable field; not only for DNA sample preparation, but also cardiac disease diagnosis (Mitsubishi) or sample preparation for DNA sequencing (Life Technologies).

How will PSS contribute to the society in the future ?

■ **Promote fully automated diagnostic systems in various research and laboratory specialities (combining PSS original reagent and consumables)**

geneLEAD®

Fully automated NAT system -sample extraction with amplification and detection

-Virus detection of infectious disease *(HIV/HBV/HCV, HPV, etc.)*
-Personalized medicine *(K-ras, EGFR, BCL-ABL, IL28B, CYP etc.)*

LuBEA®

Multiplex ELISA / DNA typing

-Thyroid hormone *(TSH, T3, T4, FT3, FT4 etc.)*
-Tumor Maker
-Allergy Test *(Specific IgE)*
-Cytokine

SpeLIA

Clinical chemistry

-Veterinary Clinic *(Canine CRP,TBA, NH3 etc.)*
-Clinical Chemistry *(γ-GTP, GOT, HDL,, LDL etc.)*

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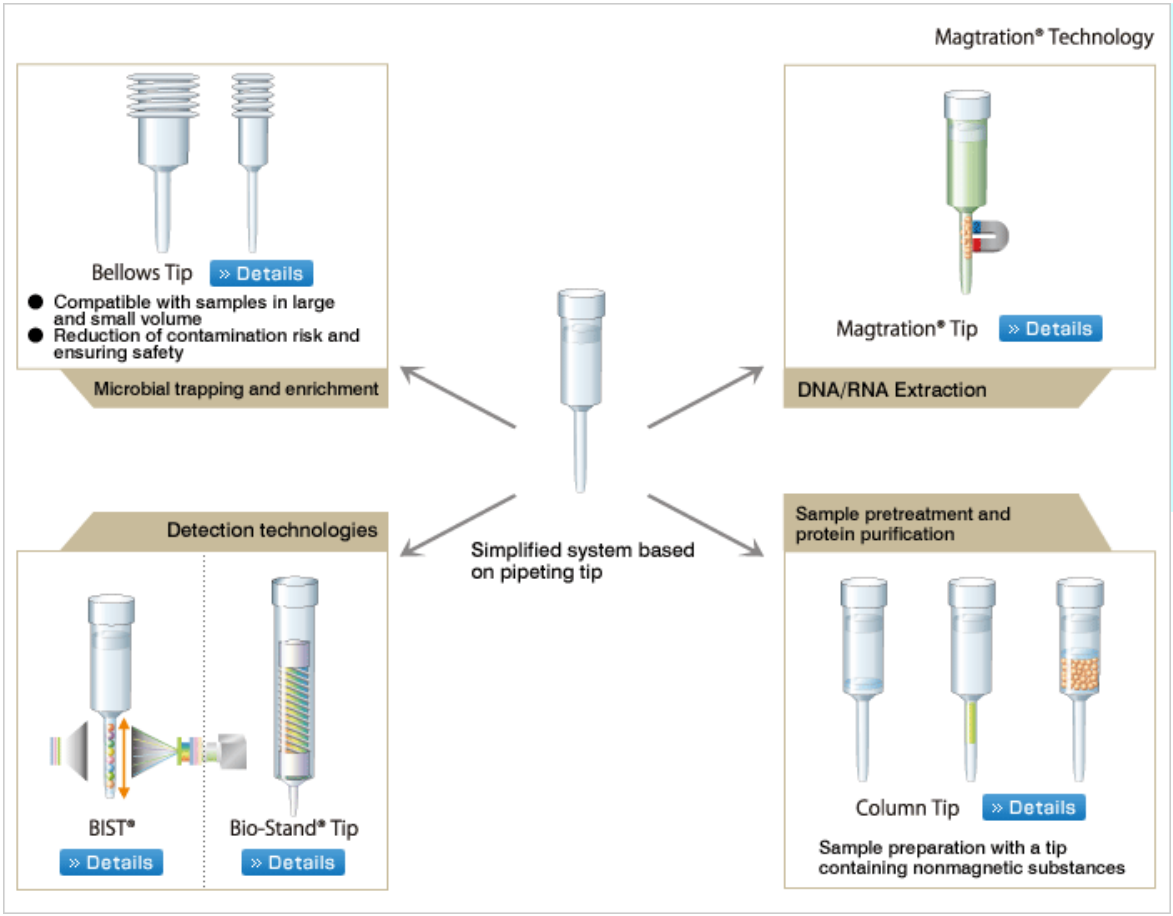
Core Technologies

Technology Concept: “APiT”

■ **Simplified dispensing system with the concept of ①SIMPLE ②COMPACT ③EASY MAINTENANCE**

PSS website > Technologies > Concept

PSS Automated Technologies: All Process in Tip Technology (APiT®)



New Technology!

MasterTip®

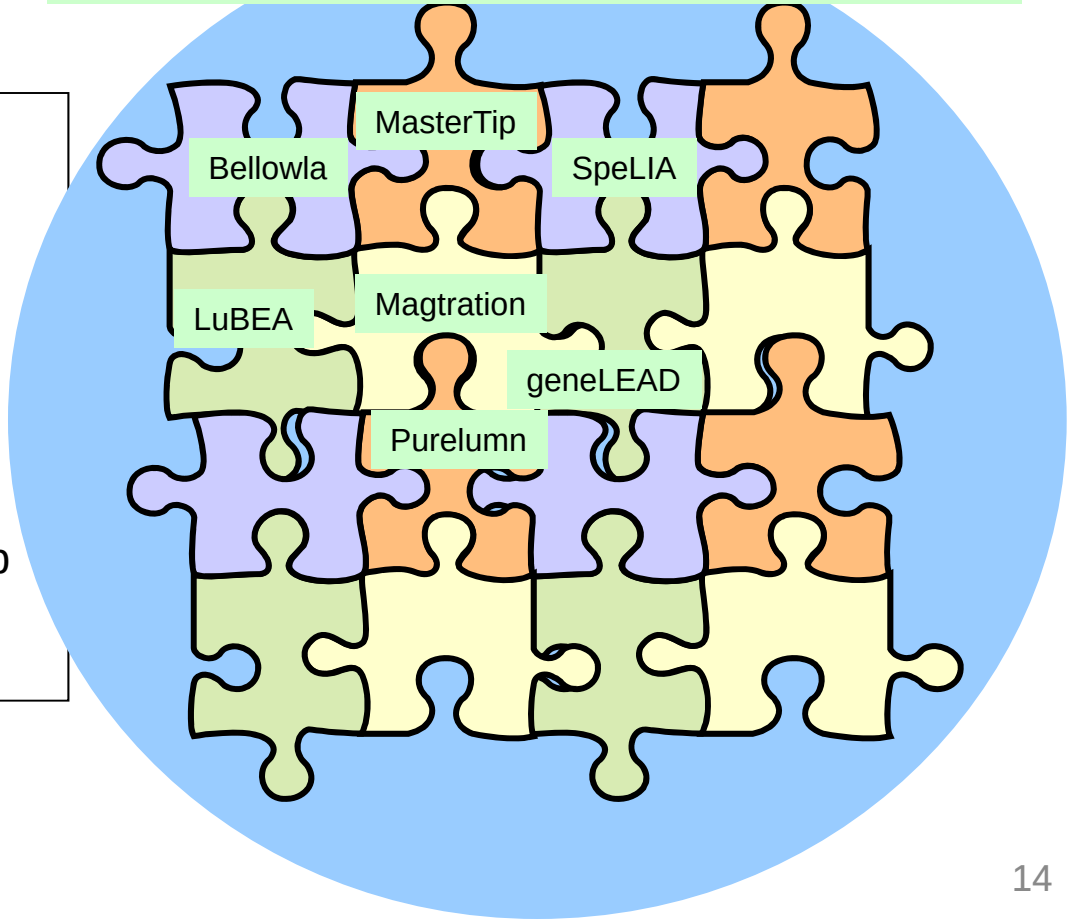
Worldwide Patent Strategy; Combined patent for system integration

■**Many PSS original automation technologies were applied or registered for patent worldwide.**
As of June 2013, 375 items applied & 159 items patented
(as of June 2008, 283 items applied & 68 items patented)

Combining these patents enables PSS to realize diversified and multi-purpose system integration.

●PSS's achievement through product development plan for last 10 years

Magtration:	Magnetic particle control
geneLEAD:	Gene sample to answer
LuBEA:	Multiplex immunoassay
SpeLIA :	Clinical chemistry POCT
Bellowla:	Large volume sample prep
MasterTip:	High throughput
Purelumn:	Protein purification



Possibility of PSS Original Technologies

- **Maturity and evolution of APiT technology**
- **Integration of APiT and detection technology (fluorescence, luminescence, spectrum)**
- **Development & manufacturing of pre-packed reagent cartridge that everybody can use easily**

→Launch clinical testing system focused on “Easy to use”

↓

Aim to develop and launch a system that ensures accurate results easily by “anybody, anytime, anywhere”.

geneLEAD: Fully automated genetic analysis system for molecular diagnostics

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System

Fully Automated Genetic Analysis System geneLEAD I and XII

Automatize all processes from DNA extraction, PCR setup, PCR processing/detection to results analysis

- **Employ pre-packed DNA extraction reagent cartridge**
- **Pre-packed PCR reagent cartridge also available**
- **Batch processing for up to 12 samples (1-1.5H of running time)**
- **Available for multiplex real-time PCR (up to 6-color fluorescence)**
- **Independently controlled PCR unit that makes different reagent available**
- **Fully automated capping system**
- **Barcode reader to manage samples and reagents**
- **Equipped with ultrasonic breaking unit**
- **Additional dispensing unit available for reagent making (option)**
- **User-friendly and easy operation with GUI**

Reagent

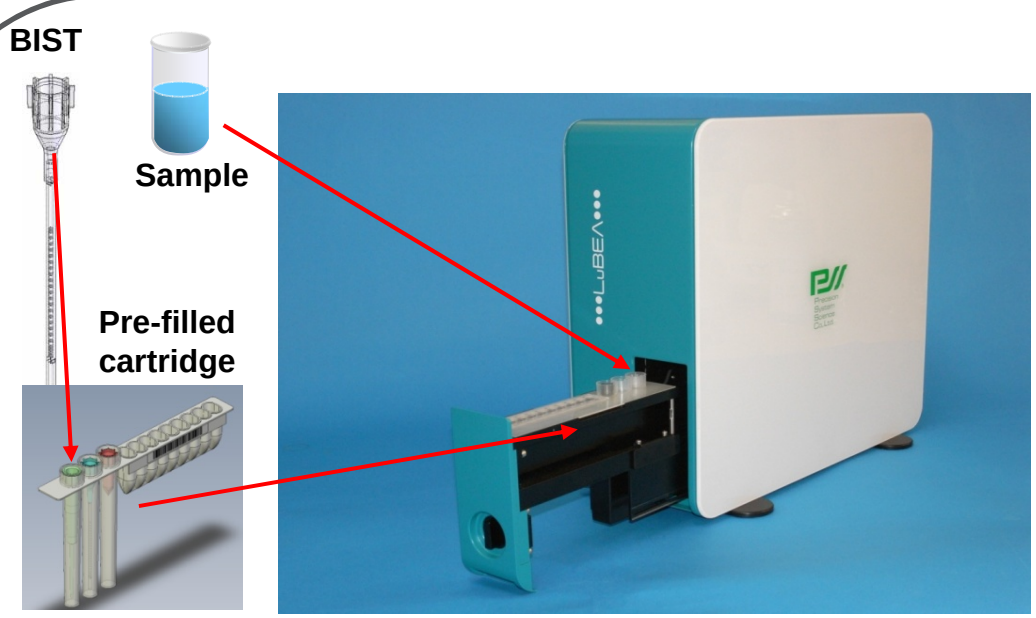
Newly developed pre-packed DNA/RNA extraction reagent cartridge for geneLEAD

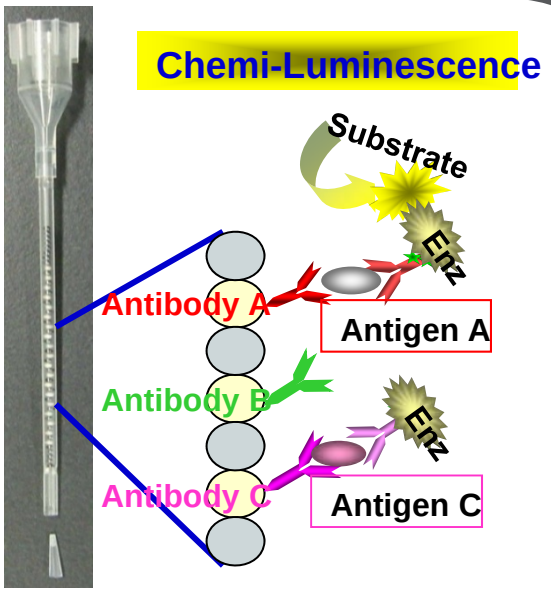
- **All reagents pre-packed in designated cartridge**
- **Necessary consumables included in the kit**
- **Possible to extract DNA/RNA from various samples in a short time (less than 25 min.)**
- **Already verified in PCR processing**

Combine with PSS's or other brand's PCR reagents

Launch in infectious disease testing and molecular diagnostics market

LuBEA: Fully automated immunological analyzer available for sequential multi-channel analysis





Multi-channel immunological analyzer: LuEBA

- Reagents are all pre-packed
- Protocol management by QR code
- Highly sensitive detection (by chemi-luminescence)
- Sample volume: 20-100 μL
- Available for both qualitative and quantitative reagents
- Analysis to results output is possible with this instrument alone
- Available for both genetic and immunological analysis
- Processing time: 10 to 30 min. (depend on testing item)

Reagents line-up (plan)

(1) TSH Reagent
(2) Virus typing (multiplex)
(3) Autoimmune disease antibody testing (multiplex)
(4) Food allergen reagent (multiplex)
(5) Genetic testing reagent (multiplex)

Applicable to genetic testing as well as immunological one

SpeLIA: Fully automated biochemical analyzer using liquid pre-packed reagent cartridge

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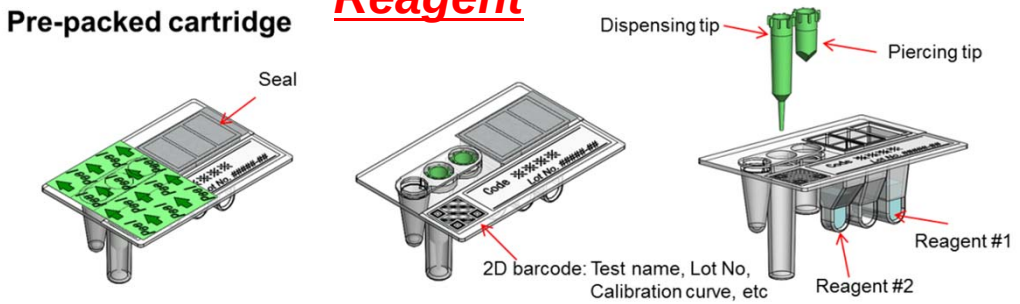
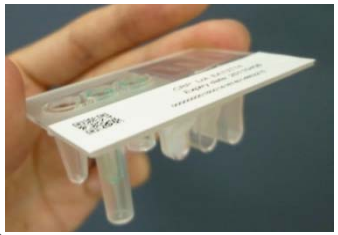
System

Reagent





Reagents

1. All reagents pre-packed (QR code contains reagent information)
2. Consumables included in reagent kit
3. Available for biochemical and latex agglutination method
4. Sample volume: min. 20 μl

Fully automated biochemical analyzer: SpeLIA

1. Pre-packed reagent cartridge with 2D barcode
2. Possible to process up to 4 reagents in 1 run
3. Available for biochemical and latex agglutination method
4. Sample volume: min. 20 μl
5. Processing time: no more than 10 min (per test)
6. Dimension: W170 x D420 x H38cm

- **Canine CRP (Latex)**
- **SAA (Latex)**
- **Canine FDP (Latex)**
- **Total Bile Acid (Biochemical)**
- **Pancreatic lipase (Biochemical)**
- **D-dimer（Latex）**

Launch in animal diagnosis market (also possible in human diagnosis)

Business cooperation field created by PSS core technologies